



PATENT
U.S. Appln. Ser. No.: 09/410,484
Attorney Docket No. NATNUT-03972

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Jan Wadstein *et al.*
Serial No.: 09/410,484
Filed: 09/30/99
Entitled: **Method Of Treating Hypertension And Reducing Serum Lipase Activity**

Group No.: 1614
Examiner: Webman

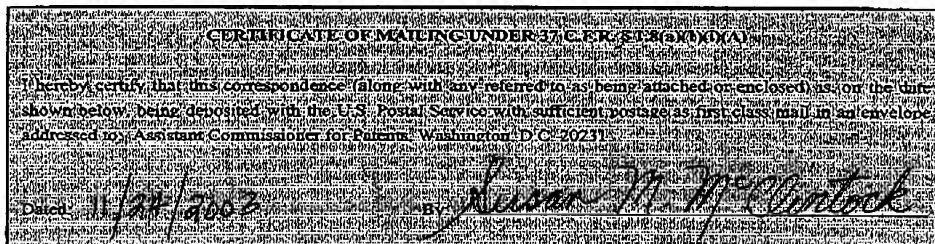
Declaration of Dr. Jean-Michel Gaullier

Assistant Commissioner for Patents
Washington, D.C. 20231

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I, Dr. Jean-Michel Gaullier, state as follows:

1. My present position is Head of Clinical Operations, Scandinavian Clinical Research, Norway.
2. I understand that the Examiner in the present case has requested data that demonstrates that CLA can reduce hypertension in the absence of weight loss.
3. The following data demonstrates that the reduction in hypertension seen in subjects taking CLA is not due to weight loss. Scandinavian Clinical Research has completed a clinical study where 180 subjects were randomized into three groups receiving 3.4 g daily of either CLA given as a triglyceride (CLA-TG) or as a free fatty acid (CLA-FFA, Tonalin) and compared to a placebo (olive oil) for one year (60 subjects per treated group).
4. Data analyses showed that at least three subjects had a statistical significant reduction of

their diastolic blood pressure (DBP) when supplemented with CLA while they had stable weight and stable body fat mass (see table below).

		Month 0	Month 12	Δ 12-0
Subject 1 Female, age 26 169 cm Non smoker Drink 1-7 glass alcohol/week CLA-FFA (# 2029)	DBP (mm Hg)	78	70	- 8
	SBP (mm Hg)	128	120	- 8
	Weight (kg)	79.40	79.43	+ 0.03
	Fat mass (kg)	34.6	33.9	- 0.7
Subject 2 Male, age 43 180 cm Smokes < 10 cigarettes/day Drink 1-7 glass alcohol/week CLA-FFA (# 2053)	DBP (mm Hg)	84	75	- 9
	SBP (mm Hg)	124	120	- 4
	Weight (kg)	84.26	84.42	+ 0.16
	Fat mass (kg)	19.8	19.4	- 0.4
Subject 3 Male, age 58 177 cm Non smoker 0 glass alcohol/week CLA-TG (# 2002)	DBP (mm Hg)	85	75	- 10
	SBP (mm Hg)	140	130	- 10
	Weight (kg)	81.33	80.99	- 0.34
	Fat mass (kg)	16.1	16.4	+ 0.3

5. I further declare that all statement made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.



Dr. Jean-Michel Gaullier

Date: October 15th, 2003